

DSJ1&2-PR Exh 527

Exhibit
Mallinckrodt-Gillies-014
2-7-19 & 2-8-19 (JA)

From: Harper, Karen
To: Davis, Howard W
Sent: 11/18/2010 1:46:10 PM
Subject: Revision of QSP Order Monitoring Attached
Attachments: Customer Review Synopsis 10_26_10 (5).doc; Distribution Letters.pdf; Keysource.pdf; QSP Order Monitoring 10_29_10.DOC; Talking Points for DEA Mtg 11-2010.doc

Howard

Please revise the QSP Order Monitoring document, incorporating recent program enhancements with recent activities --

Summary of new data analysis method is in Talking Points for DEA Mtg.doc

Customer data presented to DEA is Customer Review Synopsis.doc (we plan on continuing to extract data monthly in the same method going forward and will have the flexibility of focusing on various regional areas)

Letters to three distributors selling high amounts of Oxycodone to FL (Keysource.pdf)

Letters to all other Florida distributors (Distribution Letters.pdf)

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Global Controlled Substance Compliance Procedure	No. C/S Comp 3.0
Subject: Identification and Review of Peculiar Orders Controlled Substance Suspicious Order Monitoring Program Originator: Karen Harper Senior Manager, Controlled Substance Compliance	Revision Date: 10/29/10 Page 1 of 4

PURPOSE:

This procedure formally outlines the internal criteria and standards to identify, capture, investigate, and report suspicious orders to the Drug Enforcement Administration (DEA).

This procedure outlines the process for monitoring controlled substance orders for bulk or finished dosage products, received electronically or manually, for all active customer accounts

APPLIES TO:

Controlled Substance Customer Service Groups

Information Services Group

Controlled Substance Compliance

Security Director

REFERENCES:

- Title 21 CFR 1301.74(b)

This section defines the following obligations of a registrant. The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency

OVERVIEW:

The Drug Enforcement Administration (DEA) requires that registrants take reasonable measures to identify their customers, understand the normal and expected transactions typically conducted by those customers, and, consequently identify those transactions that are suspicious in nature

The Procedure for Identification and Review of Peculiar Orders, Suspicious Order Monitoring Program, is designed for compliance by documenting methods used to:

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Define the internal criteria for detecting Peculiar Orders for further investigation

Elevate Peculiar Orders to the level of Suspicious Order based upon investigation results and notify DEA [per CFR21 1301.74(b)].

DEFINITIONS:

- Peculiar Order: Controlled substance order that meets an internal, established criteria of 3X the average amount of product ordered during the previous 12 months by DEA reporting class
- Suspicious Order: A Peculiar Order that has been reviewed by Customer Service, Security Director, and Controlled Substance Compliance and elevated to DEA report status

REPORTS REQUIRED

- Do Not Ship List
- Peculiar Order Report
- Returned 222 Excel Spreadsheet

RESPONSIBILITIES:

Customer Service Representative

Perform the following activities for each controlled substance order:

1. Verify that the account is in good standing by reviewing the "Do Not Ship List" file on the Shared Drive
2. Assure that the order is valid by completing an evaluation and verification of an order to determine that the customer has provided a complete order
3. For CI and CII controlled substance orders
 - a. Verify customer has provided a complete DEA 222 form
 - b. Confirm that DEA 222 Purchaser address agrees with customer DEA registration license
 - c. Review the DEA 222 form for any unusual entries or anomalies
 - d. Return the 222 form to the customer if it is unacceptable, enter returned 222 information in .xls file
 - e. Obtain a "Certificate of Available Procurement Quota" from bulk API customers using a Manufacturing Registration DEA 222 Form

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- f. Obtain a "Statement of Intended Use" from customers using a Research, Compounding Pharmacy, or Analytical Lab registration DEA 222 Form
4. Review the order based on the criteria above and place the order on system hold if additional evaluation is required
5. Forward information for any order determined to be peculiar to Customer Service Manager for further investigation

Customer Service Manager

1. Review the IS system generated Peculiar Order Report which lists orders that meet the established criteria
2. Review all Peculiar Orders and document findings. Annotate Peculiar Order Report accordingly if Customer Service Manager's review authorizes shipment with no further investigation.
 - 3a. If input from Marketing required, obtain documentation from them in support of why the order should not be considered peculiar.
3. Maintains files of Peculiar Order reports and investigation findings for those Peculiar Orders that do not require further investigation
4. Refer Peculiar Orders that warrant further investigation to Security and Controlled Substance Compliance
5. Maintains the Do Not Ship List on the Shared drive which includes information about any customer for which shipment has been denied per the Suspicious Order Monitoring Program

Information Services Department

1. Programs and publishes the Peculiar Order Report which lists dosage and API orders that meet the criteria as follows:
 - a. Orders in excess of 3X the average amount of product ordered during the previous 12 months by customer, by DEA reporting class. The algorithms have been established to identify whether a customer is deviating from a normal order pattern, and/or increasing in frequency.

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Security Director

1. Investigates Peculiar Orders that have no applicable explanation for deviation from normal order pattern, size, and frequency, in conjunction with Controlled Substance Compliance
2. Consults with the business group as part of the peculiar order investigation, in conjunction with Controlled Substance Compliance
3. Reviews Peculiar Orders for comparison to DEA webpage "Drugs of Concern Listing", in conjunction with Controlled Substance Compliance
4. Responsible for reporting to DEA Peculiar Orders that have been investigated and further defined as Suspicious Orders, in conjunction with Controlled Substance Compliance
5. Maintains files of Peculiar Order reports and investigation findings for those Peculiar Orders that have required further investigation, in conjunction with Controlled Substance Compliance
6. Responsible for training internal customers on this procedure in, conjunction with Controlled Substance Compliance

Controlled Substance Compliance

1. Investigates Peculiar Orders that have no applicable explanation for deviation from normal order pattern, size, and frequency, in conjunction with Security Director
2. Consults with the business group as part of the peculiar order investigation, in conjunction with Security Director
3. Reviews Peculiar Orders for comparison to DEA webpage "Drugs of Concern Listing", in conjunction with Security Director
4. Responsible for reporting to DEA Peculiar Orders that have been investigated and further defined as Suspicious Orders, in conjunction with Security Director
5. Maintains files of Peculiar Order reports and investigation findings for those Peculiar Orders that have required further investigation, in conjunction with Security Director
6. Responsible for training internal customers on this procedure, in conjunction with Security Director